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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/538,927

06/13/2005

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EXAMINER

XIE, XIAOZHEN

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

11/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/538,927 | Applicant(s) FUJIWARA ET AL. | |
| | Examiner XIAOZHEN XIE | Art Unit 1646 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's amendment of the claims filed on 13 August 2008 has been entered. Applicant's Arguments/Remarks filed on 13 August 2008 is acknowledged.

Claims 5-7 and 9-11 are cancelled. Claims 1-4 and 8 are pending. Claim 8 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Claims 1-4 are under examination.

Election/Restrictions

Applicant continues to request rejoinder of claim 8 (Group II) in view of the claim amendment submitted on 13 August 2008. Applicant argues that since claim 1 as amended has novelty over the Morgan et al. reference, and Group II now shares a special technical feature with Group I, the two Groups satisfy the requirement for unity of invention.

Applicant's arguments have been fully considered but have not been found to be persuasive.

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In the office action mailed on 11 July 2007, it is indicated that the restriction requirement was deemed proper and made FINAL, because the 1st claimed invention has no special technical feature in view of Morgan et al., and it cannot share a special technical feature with the other claimed inventions.

Further, even Applicant has now amended claim 1 to overcome the novelty over the Morgan et al. reference, the technical feature of the amended claim 1 still lacks novelty or inventive step and does not make a contribution over the prior art (Adwani et al. (Pediatr. Cardiol., 1997, 18:143-145) (see below).

Therefore, the finality of the restriction requirement is maintained.

Claim Rejections Withdrawn

The rejection of claims 1-4 under 35 U.S.C. 102(b), as being anticipated by Morgan et al. (Clin. Cancer Res., 1997, 3:2337-2345), is withdrawn in response to Applicant's amendment of the claims to limit "administering to a patient suffering from non-ischemic heart failure".

New Grounds of Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Adwani et al. (Pediatr. Cardiol., 1997, 18:143-145).

The instant claims are drawn to a method for treating non-ischemic heart failure comprising administering to a patient suffering from non-ischemic heart failure granulocyte colony-stimulating factor (G-CSF) as the sole active ingredient in an amount effective for treating non-ischemic heart failure (claim 1), wherein the non-ischemic heart failure is caused by exacerbation of cardiomyopathy (claim 2), and the cardiomyopathy is idiopathic cardiomyopathy (claim 3), and the idiopathic cardiomyopathy is dilated cardiomyopathy (claim 4).

Adwani et al. teach a case report for treating an infant patient suffering from Barth syndrome, which is an X-linked recessive disorder comprising dilated cardiomyopathy, muscular hypotonia, and cyclical neutropenia (see Abstract, and pp. 143 section "Case Report"). Adwani et al. teach that the patient underwent heart transplant, and after that, the patient was given two doses (15 μ g once daily) of G-CSF subcutaneously on day 2 and 3 postoperatively (pp. 144, col. 1, top bridging paragraph). The dosage of G-CSF used by Adwani et al., i.e., 15 μ g once daily, meets the limitation of "an amount effective for treating non-ischemic heart failure", because the instant specification does not define such an amount, only exemplifies the amount as "the single dose of G-CSF is usually 0.1 to 100 μ g/kg" (pp. 10). Therefore, Adwani et al. anticipate the instant claims.

Claim Rejections Maintained

Double Patenting

Claims 1 and 2 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 17 of copending Application No: 10/924,197.

Applicant argues that because the independent claim 1, as amended, obviates the §102(b) rejection over Morgan et al., the non-statutory obviousness-type double patenting rejection over later-filed application 10/924,197 is the only rejection remaining, accordingly, this provisional ODP rejection should be withdrawn to permit the present earlier-filed application to issue without a terminal disclaimer.

Applicant's arguments have been fully considered but have not been found to be persuasive.

As set forth above, Applicant's amendment of the claims necessitates new ground of rejection under 35 U.S.C. 102(b). Therefore, this provisional ODP rejection can not be withdrawn.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
October 30, 2008

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646